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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,010	10/12/2000	YOSHIAKI HATA	15162/02600	6171
24367	7590	04/05/2006	EXAMINER	
SIDLEY AUSTIN LLP 717 NORTH HARWOOD SUITE 3400 DALLAS, TX 75201			BARTON, JEFFREY THOMAS	
		ART UNIT	PAPER NUMBER	
			1753	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/689,010	HATA, YOSHIAKI	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 January 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 and 8-30 is/are pending in the application.
- 4a) Of the above claim(s) 9-29 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5, 8 ,and 30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

1. The remarks filed on 13 January 2006 do not place the application in condition for allowance.

Status of Rejections Pending Since the Office Action of 11 October 2005

2. All rejections are maintained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 8, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 currently requires that the second electrode be provided "in a position at least partially opposite said first electrode". The specification and Figure 3 disclose that the second electrode (45) is positioned opposite the first electrode (44), and no disclosure is seen to support the second electrode being positioned only "partially" opposite the first electrode.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Yager et al.

Regarding claim 1, Yager et al disclose a microchip comprising a channel having internal surfaces (e.g. Figure 5, channels defined along the substrate), wherein analyzed objects travel through the channel; an optical element facing the channel to receive light from the objects, said optical element having a surface forming a part the internal surface of the channel (Figure 7; Column 9, lines 21-37 - light passes through the substrate to a detector below - the substrate itself therefore reads on the claimed “optical element”); the microchip further comprising as deflecting elements for approximating the objects in the channel to the optical element: first and second electrodes provided on top and bottom channel surfaces, respectively, positioned upstream from the detection element and opposite each other (Figures 5 and 7; pairs of electrodes 402; Column 7, lines 10-20); wherein said object is capable of being

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approximated to said optical element in a direction transverse to the length of the channel by applying an electric field to the electrodes. (Column 7, lines 17-20 discloses applying a potential across opposite electrodes, which provides this capability during the electrophoretic analysis of charged objects)

Regarding claim 30, Yager et al disclose such an optical detecting element.
(Figure 7; Column 9, lines 26-28)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 8, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhr (WO 98/28604) in view of Günther. (WO 96/13744) Since these documents

are in German, citations below are given to US 6,440,285 and US 5,933,233 respectively, which issued from the National Stage entry of these International Applications.

Regarding claim 1, Fuhr discloses a microchip comprising channel having internal surfaces wherein analyzed objects travel through the channel (Figure 2; Column 3, line 66 - Column 4, line 3); the microchip further comprising as deflecting elements for moving objects through the channel: first and second electrodes provided on top and bottom channel surfaces, respectively, positioned upstream from the detection element and opposite each other. (Figures 1 and 2; e.g. electrodes 24c and 24d; Column 6, lines 33-49) Fuhr also specifically suggests incorporating the optical detection system of Günther into his analysis system. (Column 3, lines 14-33)

Fuhr does not explicitly disclose an optical element as claimed, or structure corresponding to the limitations pertaining to this element.

Günther discloses a detection system wherein an optical element that receives light from analyzed objects (Figure 2; Wall between aperture 4 and channel 2 directly above detector 5; Column 7, line 65 - Column 8, line 5) forms a portion of the internal surface of the channel.

Regarding claim 8, Günther discloses using a waveguide to direct excitation radiation to a portion of the channel including the optical element. (Figure 4; Column 8, lines 15-22)

Regarding claim 30, Günther discloses a detector for detecting light that passes through the element. (Figure 2 or 4, detector 5)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fuhr by incorporating the detector of Günther in an appropriate detection region in a downstream portion of the channel, because Fuhr specifically suggests incorporating this detector.

In such a combination, the electrodes would inherently be capable of approximating analyzed particles in a direction transverse to the length of the channel (e.g. Trajectory a or b, in Figure 1; Column 5, line 38 - Column 6, line 12), towards the optical element, no matter which channel wall is chosen to contain the optical element associated with the detector of Günther. This combination meets all limitations of the claims.

10. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al in view of Kennedy.

Yager et al disclose a device as described above in addressing claim 1.

Relevant to claim 2, Yager et al also disclose a portion of the internal surface of the channel being defined by a groove formed on a first surface of a substrate. (e.g. Figure 5; Column 4, lines 48-55 and Column 5, lines 36-42) This substrate (e.g. a silicon wafer) has a second surface opposed to the first surface.

Relevant to claim 4, Yager et al disclose a cover plate covering the channel (Figure 5)

Yager et al do not explicitly disclose a through hole connecting a bottom of the groove to the second surface, wherein said optical element is provided in said through hole.

Kennedy discloses a microfluidic device comprising a groove disposed on a first surface, with a through hole connecting the bottom of the groove to a second surface, and the optical element being provided in said hole. (Column 7, lines 33-65; the hole in Kennedy's device passes through both substrates, providing the window in the case of opaque substrate materials. Nevertheless, it does connect the bottom of the groove to the second surface, and therefore reads on the claimed device.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Yager et al by providing a through hole through the plates of the device for the detection window, as taught by Kennedy, because it would eliminate any concerns about absorbance, scattering, or other interference from the substrate. Furthermore, in the case of a silicon or other opaque substrate, a through hole with a transparent window (i.e. optical element) would be necessary for use of a detector positioned below the substrate. Such positioning of the detector (Above or below the substrate, Yager et al Column 9, lines 26-32, Figure 5) is a matter of design choice to one having ordinary skill in the art.

Regarding claim 3, neither Kennedy nor Yager et al explicitly disclose a tapered through hole.

However, it is well within the abilities of one having ordinary skill in the art to select a shape suitable for the hole that accommodates the detection window. For instance, in *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966), the court held that the configuration (i.e. shape) of the claimed object was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.

Furthermore, both Yager et al (Column 4, lines 48-50) and Kennedy (Column 3, line 65 - Column 4, line 4) disclose forming the microfluidic devices from silicon, and conventional etching techniques (e.g. KOH) typically attack silicon anisotropically, resulting in tapering pits, trenches, or holes. Therefore, tapered through holes would inherently result from etching the silicon substrate with typical etching solutions in order to form the structure required in this combination.

11. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al in view of Manz et al and Kricka et al.

Yager et al discloses a device as described above in addressing claim 1.

Relevant to claim 2, Yager et al also disclose a portion of the internal surface of the channel being defined by a groove formed on a first surface of a substrate. (e.g. Figure 5; Column 4, lines 48-55 and Column 5, lines 36-42) This substrate (e.g. a silicon wafer) has a second surface opposed to the first surface.

Relevant to claim 4, Yager et al disclose a cover plate covering the channel (Figure 5)

Yager et al do not explicitly disclose a through hole connecting a bottom of the groove to the second surface, wherein said optical element is provided in said through hole.

Relevant to claim 2, Manz et al teach the construction of a detector (for incorporation into miniaturized separation systems (Column 2, lines 58-60), in which a substrate (Figure 4, plate 5) has a second surface (top, as shown in Figure 4) opposed to a first surface and has a through hole (11) with an optical element (13) disposed therein.

Relevant to claim 3, Manz et al disclose the through hole (11) having a tapered shape. (Figure 4)

Relevant to claim 2, Manz et al do not explicitly disclose the channel being defined in part by a groove on the first surface (interior) of substrate (5).

Kricka et al disclose formation of channel grooves in a microfluidic device on the same substrate as through-holes that provide access to the channels. (i.e. the channel is defined by a groove on one surface and holes connect the bottom of the groove to the opposing surface - see Figures 2 and 4) The device of Kricka et al is made of the same material (crystalline silicon) as used by both Manz et al and Yager et al.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Yager et al by replacing their detector with an on-chip detector cell, as taught by Manz, because Manz teaches its effectiveness in increasing detection sensitivity in miniaturized separation apparatuses (Yager et al is an example) by providing an increased detection path length. (Column 2, lines 49-60)

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the combined device of Yager et al and Manz et al by fabricating the channel on the inward-facing surface of substrate 5 (Manz), instead of plate 6, as taught by Kricka et al, because it would simplify device construction by allowing channel paths to be directly defined by through hole locations (i.e. channel etching could be guided by hole locations after through-hole etching), and eliminating concerns over the alignment of plates relative to each other. Furthermore, the choice of which plate(s) to use in providing through holes for communication with the channel would have been within the level of ordinary skill in the art.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al in view of either Weigl et al or Swerdlow et al.

Yager et al discloses a device as described above in addressing claim 1.

Yager et al do not explicitly disclose the optical element comprising a condenser lens.

Weigl et al disclose a detector comprising a condenser lens useful in combination with microfluidic devices. (Figure 2, lens 50, cartridge 34 corresponds to the microfluidic device - see background section; also Column 4, lines 16-40)

Swerdlow et al describe a detector comprising a lens that "condenses" light emitted over a range of angles into a converging beam, wherein the detector is used in combination with a capillary flow cell. (Figure 3, objective lens)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Yager et al by replacing their detector with the detector taught by Weigl et al, because they teach its usefulness in detecting multiple analytes at multiple wavelengths (Column 3, lines 7-15), and electrophoresis devices, such as that of Yager et al, are often used for analysis of multicomponent samples.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Yager et al by replacing their detector with the detector described by Swerdlow et al, because they teach its extremely high sensitivity. (Abstract)

In these rejections, given the open language of the claims (i.e. "comprising") the limitation "optical element having a surface forming part of the internal surface of the channel" is read broadly such that a detection system comprising both a window that forms part of the channel's internal surface and a condenser lens is held to read on the claim limitations.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al in view of Manz et al.

Yager et al disclose a device as described above in addressing claim 1.

Yager et al do not explicitly disclose a device comprising a light guide for guiding light from an external source to a prescribed area of the channel, wherein the optical element is provided at the prescribed area.

Manz et al teaches the construction of a detector for incorporation into miniaturized separation systems (Column 2, lines 58-60) comprising a light guide (Figure 4, Fiber 12) for guiding a light from an external source to an area of the channel (the portion between Fibers 13 and 13), wherein the element (13) is provided at the prescribed area.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Yager et al by replacing their detector with an on-chip detector cell, as taught by Manz et al, because Manz et al teach its effectiveness in increasing detection sensitivity in miniaturized separation apparatuses (Yager et al is an example) by providing an increased detection path length. (Column 2, lines 49-60)

Response to Arguments

14. Applicant's arguments filed 13 January 2006 have been fully considered but they are not persuasive.

Regarding the rejection under 35 U.S.C. §112(1), the Examiner must differ with Applicant's characterization of Figure 3. No portion of the second electrode (45) is shown to be only "partially opposite" the first electrode (44). At any given position in electrode 45, a portion of electrode 44 is present on the opposite side of the channel. This is "opposite", not "partially opposite". Given one interpretation, electrode 44 might possibly be said to be "partially opposite" electrode 45, since its rightmost portion extends beyond electrode 45, but Applicant provides no basis in the specification describing what precisely is intended by the term "partially opposite", and therefore the written description requirement has not been met.

Regarding Yager et al, Applicants argue that the reference does not disclose "a second electrode provided to face said channel at an upstream side of said optical element . . .", given the Examiner's interpretation that the cover of the device is considered to read on the claimed optical element. The Examiner considers Applicant's reading to be narrower than justified by the claim language. In the device of Figure 7 of Yager et al, for example, materials migrate from left to right as illustrated. Clearly, the electrodes positioned farthest to the left are at a relative "upstream side of said optical element", compared to the electrodes and device sections farther to the right. Nothing in the claim language limits the recited "upstream side" to refer to a separate device portion entirely upstream of the optical element, in contrast to Applicant's arguments.

Applicant further argues that Yager et al fail to disclose applying an electric between the electrodes such that an object is "approximated to said optical element in a direction transverse to a length of said channel." Such arguments simply cannot be

persuasive, as they are entirely directed to the intended use of the device. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant disputes the characterization of the wall 4 of Günther as an optical element, asserting that it does not transmit light and has no “optical power”. This position is simply unsupportable. At the outset, given the geometry of the device of Günther, light must clearly pass through the wall portions adjacent the source 3 and detector 5 - otherwise the detector could not function. Günther discloses that this is the case at Column 5, lines 5-13. Applicant asserts that the silicon used is not transparent to visible light, which is not entirely true. Visible light penetrates crystalline silicon to a finite depth, and a significant portion of visible light will pass through a window of silicon that is thin enough (e.g. microns or less). In any event, Günther’s disclosure is not limited to silicon (Column 5, lines 14-16), nor is it limited to visible light. The argument pertaining to the “optical power” of the optical element carries no weight, since no limitation to this is recited in the claim. In any event, the term “optical element” must be given the broadest reasonable interpretation, which would be taken to be any element that reflects, transmits, absorbs, refracts, or otherwise interacts with light in any way pertinent to the structure or operation of the device.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 9:00 am – 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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JTB
31 March 2006

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